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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,035	05/03/2001	John Bertin	07334-268001	6469

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,035	BERTIN, JOHN	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 18, drawn to a polynucleotide, vector and a cell for the polynucleotide directed biosynthesis of the polypeptide, are classified in class 536, subclass 23.1, class 435, subclass 320.1 and 69.1.

II. Claims 13-16, drawn to a polypeptide are classified in class 530, subclass 350^{+}, and class 514, subclass 2, and class 424, subclass 192.1.

III. Claim 17, drawn to an antibody binding to the polypeptide, is classified in class 530, subclass 387.1.

IV. Claims 19, 20 and 22, drawn to a method of detecting a polypeptide comprising identifying a polypeptide-binding compound, and a kit (the kit does not contain the polypeptide) comprising the compound, are classified in class 435, subclasses 7.1, 69.1 and 326, class 530, subclass 350, and class 514, subclass 2.

V. Claim 21, drawn to a method for detecting the presence of a nucleic acid, is classified in class 536, subclass 23.1, class 437, subclass 94. and class 514, subclass 44.

VI. Claims 23 and 24, drawn to a method for modulating the polypeptide activity, classified in class 530, subclass 350, class 424, subclass 9.1, class 435, subclass 7.1, and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention II is drawn to polypeptide and Invention III to an antibody while Invention I is drawn to a polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to

exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention I is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to a cell into which polynucleotides is transferred and a vector where the polynucleotide is bale to directing biosynthesis of the gene product, which process would have been searched in class 435 subclass 69.1. Invention III is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification.

Invention I (polynucleotide) and Invention III (antibody) are distinct from each other because of the materially different structures of the compounds claimed. The Invention I is drawn to polynucleotide, while Invention III is drawn to immunoglobulin, a polypeptide. The biopolymers that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The nucleic acid is composed of deoxyribonucleotides linked by phosphodiester bonds and forms a double helix as a stable conformation that is a functionally structural characteristic. While antibody is composed of amino acid residues linked by peptide bond. Thus, biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions II (polypeptide) and Invention III (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Inventions IV, V and VI are related as different and/or distinct methods. These two methods differ with respect to method steps, end-products, targets, and ingredients; therefore, each method is patentably distinct.

Invention I is unrelated to Inventions IV and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide can be immobilized on DNA microarray chip for genomic typing

analysis which mechanism differs from action of detecting polypeptide and mechanism of modulating the polypeptide.

Invention I is related to Inventions V as product processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be immobilized on DNA microarray chip for genomic typing analysis, for example.

Invention II is related to Inventions V as product processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be immobilized on DNA microarray chip for genomic typing analysis, for example.

Invention II is related to Inventions IV and VI as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be immobilized on a gold-chip on surface plasma resonance to analyze real time protein-protein interaction, for example.

Invention III is unrelated to Invention V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the mechanism of detecting polynucleotide is distinct from that of protein-protein interaction.

Invention V is unrelated to Invention IV, V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the mode of action of the antibody is different/distinct from the mechanism of the non-immunoglobulin compound binding to the polypeptide or the mechanism of detecting nucleic acid molecule.

Additional Election Under 35 USC 121

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed polynucleotide or polypeptide to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

If Group I is elected, applicant is required under 35 US 121 (1) to elect one polypeptide sequence and one corresponding nucleotide sequence from claims 1-9 and 18 since the polypeptide sequences or the polynucleotide sequences are structurally distinct from one another, respectively.

If Group II is elected, applicant is required under 35 US 121 (1) to elect one polypeptide sequence from claims 13-16 since the claimed polypeptide are structurally distinct from one another.

If Group III is elected, applicant is required under 35 US 121 (1) to elect one polypeptide from claim 17 for binding to the claimed antibody since the polypeptides are structurally distinct from one another and have resulted in distinct/different antigenicity thereof.

If Group IV or Group VI is elected, applicant is required under 35 US 121 (1) to elect one polypeptide from claims 19-20 and 22 since the polypeptides are structurally distinct from one another; thus, the methods of use of each polypeptide are patentably distinct from one another.

If Group V is elected, applicant is required under 35 US 121 (1) to elect one polynucleotide from claim 21 since the polynucleotides are structurally distinct from one another which determines that the methods of use of each polynucleotide are patentably distinct from one another.

In the above, the response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Samuel W. Liu, Ph.D.
September 12, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER